

Exhibit B

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Biomedical Device Consultants &
Laboratories of Colorado, LLC,

Plaintiff,

v.

TA Instruments – Waters, LLC,

Defendant

Civil File No. 0:17-cv-03403

**DECLARATION OF CRAIG
WEINBERG IN SUPPORT OF
MOTION FOR PRELIMINARY
INJUNCTION**

I, Craig Weinberg, hereby declare and state as follows:

1. I am the President and CEO of Plaintiff Biomedical Device Consultants & Laboratories of Colorado, LLC (“BDC”). I make this Declaration in connection with BDC’s motion for a preliminary injunction. I have personal knowledge of the matters set forth below and, if called as a witness, I could and would testify as follows.

Background

2. I received my Ph.D. in the area of Mechanical Engineering with a focus in cardiovascular fluid dynamics from the University of Colorado in 2003. In early 2011, I began to serve on the US sub-committee and then, as of January of 2015, began serving on the parent international committee ISO/TC 150/SC 2/WG 1, which is the group that creates the international guidance documents for design verification/validation evaluation of heart valves and heart valve repair devices. As a result, I am very familiar with all the commercially available products that are part the functional performance evaluation, both real-time and accelerated, utilized during the verification/validation testing of the

associated devices.

3. In 2006, I joined BDC as its president. In about February 2008, a team of three people—myself, Benjamin McCloskey, and Dr. Steven Weinberg—began researching and designing a new prosthetic heart valve and venous valve durability testing system. The dedication of a three person research team to this project was a significant investment for BDC. Though BDC currently has five or six employees solely devoted to working on its testing equipment business, back at the time of the invention in 2008, the entire company was only on the order of five full time employees.

4. The nature of BDC's business requires that it make these types of significant investments in research and development. BDC's customers are those that wish to test medical devices, often the medical device manufacturers themselves testing the device to obtain regulatory approval. The medical device industry is an innovative industry—new and improved medical devices enter the market all the time. These new devices often require state of the art testing systems for their evaluation. For example, prosthetic heart valves have seen significant improvements in recent years resulting in larger sizes and different methods of for securing in place within the human body (e.g. transcatheter heart valves). This has required similar innovations in the equipment available to test the valves. Therefore, to stay competitive, BDC must keep pace with the innovation of both its customers and its competitors.

5. Our research, with respect to heart valve durability test equipment, eventually led to the issuance of four patents, U.S. Patent Nos. 8,584,538 (“the ’538 Patent”), 8,627,708 (“the ’708 Patent”), 9,186,224 (“the ’224 Patent”), 9,237,935 (“the

'935 Patent") (collectively, "the Patents-in-Suit"). I am a named inventor for all four patents.

BDC's Innovative VDT-3600i System is Market Leading Test System

6. Before the Patents-in-Suit, heart valve durability testing systems on the commercial market used drive motors that resulted in minimal control of the differential pressure rate and spikes associated with valve closure that could result in unnecessary early deterioration of the test valves and potential false test failures. To better manage valve closing dynamics and differential pressure spikes, and thus better comply with the durability testing standards, myself and the co-inventors of the Patents-in-Suit developed a novel test system that placed an excess volume area on the outflow side of a test sample valve. We also developed a method of operating the test system to help control and minimize differential pressure loading and associated spikes.

7. The reduction in differential pressure spikes during closure in the accelerated flow system was further aided by the use of a "compliance chamber." A compliance chamber is an area usually filled with air or gas within a test system that permits a change in its volume with an associated change in system pressure. In our design, we positioned a compliance chamber downstream of the test sample. It acts similar to a spring and stores pressure in the system during the "drive" phase (the phase the opens the test valve) and then releases it during the "return" phase (the phase that closes the valve).

8. The Patents-in-Suit revolutionized the market for heart valve durability testing systems by providing an accelerated testing device with a compliance chamber on

the outflow side of the valve and a non-symmetrical waveform driving signal. BDC has commercialized the Patents-in-Suit through a product known as the VDT-3600i heart valve durability tester.

9. The VDT-3600i has been a tremendous success. When it was released it was a unique and differentiated product. It was the only testing system on the market that used a non-regular signal input to the drive motor and provided an excess volume area in a return chamber, downstream of the valve to store fluid during the driving phase of the system. This excess volume area and use of a non-regular driving waveform are significant improvements in accelerated test system design. The signal form better controlled the test valve loading and reduced the differential pressure spike while better meeting the test standard for holding a pressure differential across the valve without excessive pressure loading. The excess volume area further provided for storage of pressure which improved our system's ability to test heart valves at an accelerated rate in an efficient and controlled manner.

10. The market for heart valve durability testing systems is highly specialized and therefore is also very small. There are only four competitors in the market. These competitors currently are my company BDC, Defendant TA Instruments-Waters LLC ("TA Instruments"), Dynatek Labs, and ViVitro Labs. When the VDT-3600i was released, the only competitors were Dynatek and ViVitro. Dynatek's system, however, used old, outdated technology. As a result, it was, and is, not considered a viable alternative in the marketplace for the latest valve technology and currently has few sales, if any. Similarly, ViVitro's testing system relies on movement of an artificial heart valve

through fluid to create the valve opening and closing, not movement of fluid through a valve, which is thus not testing the valve in clinically representative manner. Once the VDT-3600i entered the market, ViVitro's technology was deemed not commercially relevant or equivalent to the VDT-3600i. Therefore, as a superior and unique product, the VDT-3600i rapidly (within five years) became the industry standard for heart valve durability testing systems.

11. BDC's VDT-3600i currently has about an 80-90% share of the worldwide market for heart valve durability testing systems. Market share in the heart valve durability testing equipment market is extremely important due to the incumbency effects. A single testing system can only test a few devices at a time. (For example, both BDC and TA Instruments sell systems that test a maximum of six prosthetic heart valves at a time). To bring a new prosthetic valve device to market, however, medical device manufacturers need testing data from many, often dozens, of sample devices. Therefore, testing system customers need multiple systems. Customers will generally purchase a single testing system and run a short pilot program. If the pilot test is successful, the customer will then purchase more of the same test systems from the same manufacturer as part of a larger testing program for commercial use.

12. Customers generally do not buy testing equipment for a single device from multiple sources in order to avoid introducing additional testing variables (i.e., differences between testing machines from different suppliers) into the test data that would be submitted to the FDA, or international regulatory agencies. The lifespan of valve durability testing equipment is often ten to fifteen years, meaning that once a

customer has decided which testing equipment to use, it will likely be a long time before a competitor has the opportunity to usurp the place of an incumbent.

13. A company's ability to maintain market share is crucial to its long-term success. As I previously mentioned, research and development is vital to a company in this industry so that it can keep pace with its customers and competitors. In order to fund this research and development, BDC uses part of its revenue from its sales to fund its research and development for new devices. The VDT-3600i is of particular significance to BDC because it is BDC's best-selling test system. Therefore, lost sales of the VDT-3600i will negatively impact all of BDC's business because it will have less revenue to fund its research and development across its platform.

14. In this industry, market share is also often linked to reputation for innovation. As I mentioned before, innovation is extremely important. Accordingly, customers often make decisions based on reputation for innovation, and a testing system supplier's long-term success is dependent on that reputation. BDC has a reputation for innovation and associated customer goodwill. For example, the BDC website has numerous customer testimonials discussing BDC's work to innovatively solve problems posed by customers. <http://www.bdclabs.com/about-us/client-testimonials/>. Contributing to BDC's reputation for innovation is the fact that the VDT-3600i is a differentiated, patented product for heart valve durability testing.

DuraPulse System Threatens VDT-3600i Market Position

15. However, the VDT-3600i is no longer a completely unique product because TA Instruments sells a similar system that infringes the Patents-in-Suit known as the

DuraPulse Heart Valve Test Instrument (the “DuraPulse”).

16. I first became aware of the DuraPulse in about October 2013, when I observed a prototype of the DuraPulse system at a tradeshow. The DuraPulse is part of a product line known as ElectroForce, which at that time was being developed by Bose Corporation (“BOSE”). Based on my observations of the DuraPulse in late 2013, I was concerned that it may infringe those of the Patents-in-Suit issued at that time. In July 2014, I learned that BOSE was offering the DuraPulse for sale. I sent a letter to BOSE notifying it that the DuraPulse may infringe the ’538 Patent and the ’708 Patent, and would infringe the ’935 Patent once issued (the patent application was still pending at the time). The application for the ’224 Patent had not yet been filed. At that time, I did not have detailed information about the operation of the BOSE DuraPulse and thus could not definitively determine many aspects of its operation.

17. BOSE responded to my letter saying that it did not infringe the ’538 and ’708 Patents and refused to address the application for the ’935 Patent, as it had not yet issued. At the time, I did not want to file an infringement lawsuit or seek an injunction for several reasons. I had only limited information about the operation of the DuraPulse system and did not have access to a product. BDC also still had a patent application pending that I thought might warrant inclusion in a potential lawsuit. Finally, at the time, BOSE’s potential infringement was not an imminent threat to the market position of VDT-3600i. BOSE’s sales and marketing of the DuraPulse appeared to be negligible and I was not aware of any lost sales. As patent litigation is very expensive and BOSE is a much larger company than BDC (both now and at the time), filing a lawsuit based on

limited information and with uncertainty about any actual damage made little sense at the time.

18. In late May 2015, BOSE sold the ElectroForce division and product line, which included the DuraPulse, to TA Instruments. After acquiring ElectroForce, TA Instruments dramatically increased its marketing efforts for the DuraPulse.

19. I studied the promotional materials for DuraPulse that TA Instruments had made available. It became clear to me that the DuraPulse infringed the Patents-in-Suit, especially the patents that had recently been issued (the '224 Patent, which issued on November 17, 2015, and the '935 Patent, which issued on January 19, 2016). Based on information from its marketing materials, TA Instruments makes, sells, and offers to sell the DuraPulse in the United States. TA Instruments also uses the DuraPulse for heart valve durability testing. It makes claims regarding the efficacy of the DuraPulse system for testing in its promotion materials. In order to make these claims, it must have itself used the DuraPulse system. TA Instruments also advertises to customers that the DuraPulse can be used for heart valve durability testing, and instructs customers how to use the DuraPulse for that purpose (which is its only advertised purpose).

20. On February 23, 2016, I sent a letter to TA Instruments notifying it of its infringement of the Patents-in-Suit. Because BDC is a small company and patent litigation is expensive both in terms of money and in terms of employee time, I thought it would be prudent to negotiate a resolution with TA Instruments as long as the terms of any potential agreement that could protect BDC's market position in terms of reputation, price, and innovation. To that end, BDC and TA Instruments engaged in a series of

communications concerning TA Instruments' defenses to BDC's claims for over a year.

21. While these settlement discussions were ongoing, TA Instruments' increased marketing efforts for the DuraPulse began to pay off and its infringement became a real threat to BDC.

22. In February 2017, while the parties were exchanging settlement correspondence, BDC lost a sale of the VDT-3600i to TA Instruments' DuraPulse system in head-to-head competitive bidding for a customer. The customer told me that price was a consideration in why the customer purchased from TA Instruments and not BDC. This was surprising because BDC's list price for the VDT-3600i starts at roughly \$71,000 and the DuraPulse starts at \$100,000. In order to undercut BDC's price, TA Instruments is apparently offering discounts to customers to attract business and "buy" market share. BDC is now experiencing price pressure, potential customers for the VDT-3600i are asking for price concessions. As a result of the timing of this sale and the content of TA Instruments' settlement communications, it became clear to me that TA Instruments was simply trying to draw out the discussion while improving its position in the market.

23. Even one lost sale to TA Instruments is a significant threat to BDC because the market is very small. Systems are expensive, and BDC only sells between [REDACTED] systems a year. The market is therefore sensitive to change. With TA Instruments winning bids against BDC, BDC is in immediate threat of losing its market lure as a unique, patented product. This will lead to BDC losing more market share and losing its reputation for innovation. BDC will also have less revenue to dedicate to research as a result of less sales and potentially being forced to lower its prices to stay

competitive.

24. In addition, I became aware of U.S. Patent No. 9,662,210 (“the ’210 Patent”), which was originally applied for by Bose in January 2014 and acquired by TA in May 2015. The ’210 Patent describes the operation of an accelerated valve test system that looks like the DuraPulse from the figures. I recently (September 2016) had the opportunity to observe the DuraPulse system in operation, and my observations confirmed that the ’210 Patent describes the operation of the DuraPulse. The description of the DuraPulse in the ’210 Patent confirms that the system infringes the Patents-in-Suit and also confirms that the system has been used by TA Instruments itself (not just its customers). TA Instruments has continued to make use, offer for sale, and sell the DuraPulse even after being specifically advised in February 2016 that such activities would infringe the claims of the Patents-in-Suit.

I declare under the penalty of perjury that the foregoing is true and correct.

Executed on November 22, 2017 in Wheat Ridge, Colorado.

/s/ Craig Weinberg
Craig Weinberg